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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,452	06/03/2005	Luca Barella	K21516USWO	3265

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EXAMINER	
WINSTON, RANDALL O	
ART UNIT	PAPER NUMBER
1655	
MAIL DATE	DELIVERY MODE
07/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,452	BARELLA ET AL.	
	Examiner	Art Unit	
	Randall Winston	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made of receipt and entry of the response to the amendment filed on 03/11/2008. Examiner acknowledges that claims 1-24 have been cancelled. Claims 25-31 have been examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25 and 30 as amended stands rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabled for a method of treatment of symptoms or pathologies associated with androgen signaling which comprises administering to a subject in need of such treatment for therapy an effective amount of lycopene, the specification does not enable any person skilled in the art to prepare a method of prevention of symptoms or pathologies associated with androgen signaling which comprises administering to a subject in need of such treatment for therapy or prophylaxis an effective amount of lycopene.

The factors to be considered in determining whether undue experimentation is required are summarized in In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; © the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of

experimentation needed to make or use the invention based on the content of the disclosure.

Applicant claims a method of prevention of symptoms or pathologies associated with androgen signaling which comprises administering to a subject in need of such treatment for therapy or prophylaxis an effective amount of lycopene. Please note the term prevent is an absolute definition which means to stop from occurring and, as such, requires a higher standard for enablement than the instantly disclosed invention. Applicant has only demonstrated in the experiment section on pages 13-14 of the specification, a method of treatment of symptoms or pathologies associated with androgen signaling which comprises administering to a subject in need of such treatment for therapy an effective amount of lycopene. Applicant's specification, however, fail to provide guidance and/or working examples whereby applicant prepares a method of prevention of symptoms or pathologies associated with androgen signaling which comprises administering to a subject in need of such treatment for therapy or prophylaxis an effective amount of lycopene.

Accordingly, it will take undue experimentation without reasonable expectation of success for one of skill in the art to a method of prevention of symptoms or pathologies associated with androgen signaling which comprises administering to a subject in need of such treatment for therapy or prophylaxis an effective amount of lycopene.

Applicant argument has been carefully considered but it is not deemed persuasive. Applicant argues the examiner's interpretation of prevention is unreasonable. The examiner has cited no dictionary definition, scientific treatise, or case law as the basis for interpreting a "method of preventing" disease to require "absolute and complete" prevention of the disease.

Although Applicant argues that examiner has cited no dictionary definition, scientific treatise, or case law as the basis for interpreting a "method of preventing" disease to require "absolute and complete" prevention of the disease, Applicant argument is not found persuasive because examiner restates that the term prevent is an absolute definition which means to stop from occurring and, as such, requires a higher standard for enablement than the instantly disclosed invention. Therefore, Applicant's specification, however, fail to provide guidance and/or working examples whereby applicant prepares a method of prevention of symptoms or pathologies associated with androgen signaling which comprises administering to a subject in need of such treatment for therapy or prophylaxis an effective amount of lycopene. Applicant has only demonstrated in the experiment section on pages 13-14 of the specification, a method of treatment of symptoms or pathologies associated with androgen signaling which comprises administering to a subject in need of such treatment for therapy an effective amount of lycopene. Accordingly, it will take undue experimentation without reasonable expectation of success for one of skill in the art to a method of prevention of symptoms or pathologies associated with androgen signaling which

comprises administering to a subject in need of such treatment for therapy or prophylaxis an effective amount of lycopene.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 25 as amended stands rejected under 35 U.S.C. 102(a) as being anticipated by Lorant et al. (US 623769) for the same reasons set forth in the previous OFFICE ACTION which are restated below.

Applicant claims a method of treatment of pathologies associated with androgen signaling which comprises administering to a subject in need of such a prophylaxis an effective amount of lycopene.

Lorant anticipates the claimed invention because Lorant teaches an effective amount of lycopene is administered to a subject in need thereof to treat pathologies associated with androgen signaling such as acne (please note since applicant is claiming the use of lycopene as a prophylactic, the administered of lycopene as a prophylactic to a subject in need thereof would read on treating or preventing any and/or all diseases instead of only treating or preventing the claimed pathologies associated with androgen signaling) (see e.g. entire patent

including column 3 lines 5-10). Therefore, the reference is deemed to anticipate the claimed invention.

Applicant argument has been carefully considered but it is not deemed persuasive. Applicant argues that the examiner failed to identify wherein Lorant "a method of prevention of pathologies associated with androgen signaling..." as claimed is disclosed.

Although Applicant argues that the examiner failed to identify wherein Lorant "a method of prevention of pathologies associated with androgen signaling..." as claimed is disclosed, Applicant argument is not found persuasive because since applicant is claiming the use of lycopene as a prophylactic, the administered of Lorant's lycopene as a prophylactic to a subject in need thereof would read on treating or preventing any and/or all diseases instead of only treating or preventing the claimed pathologies associated with androgen signaling. Moreover, Lorant anticipates and/or reads on the claimed invention because Lorant teaches an effective amount of lycopene is administered to a subject in need thereof to treat pathologies associated with androgen signaling such as acne. Therefore, the Lorant's reference is deemed to anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 25-31 as amended stand rejected under 35 U.S.C. 103(a) as being unpatentable over Lorant et al. (US 6623769) in view of De Salvert (US 5827520) for the reasons set forth the previous OFFICE ACTION which are restated below.

Applicant claims a method of treatment of pathologies associated with androgen signaling which comprises administering to a subject in need of such a prophylaxis an effective amount of lycopene and further comprising vitamin c whereas the claimed active ingredients of lycopene and vitamin c are administered in various amounts.

Lorant teaches an effective amount of lycopene is administered to a subject in need thereof to treat pathologies associated with androgen signaling such as acne (see, e.g. entire patent including column 3 lines 5-10). Lorant does not expressly teach the combination of lycopene and vitamin c administered to a subject in thereof to treat pathologies associated with androgen signaling such as acne.

De Salvert benefically teaches vitamin c treats pathologies associated with androgen signaling such as acne (see, e.g. column 4 lines 50-55).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Lorant to include the claimed active ingredient of vitamin c as taught by De Salvert within Lorant's method teachings because the above combined reference would create the claimed

invention of a method of treatment of symptoms or pathologies associated with androgen signaling such as acne which comprises administering to a subject in need of such treatment for therapy an effective amount of the combination of lycopene and vitamin c. Moreover, as discussed in MPEP Section 2114.06, "it is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose (i.e. to treat acne), in order to form a third composition to be used for the same purpose..." Furthermore, the adjustment of other conventional working conditions (e.g. the claimed active ingredients within various amounts within the claimed composition's method of use and the amounts and times per day the claimed composition's method is administered), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Applicant's arguments have been carefully considered but they are not deemed persuasive. Applicant argues Lorant either alone or in combination with de Salvert does not disclose or suggest "a method of prevention...." or a method of preventing..." as recited by currently amended claims 25 and 30, respectively. Therefore, the rejection, Lorant in view of de Salvert, as asserted by the Examiner, falls short of disclosing or suggesting the currently claimed method. For this reason also, the rejection should be withdrawn.

Although Applicant argues that Lorant either alone or in combination with de Salvert does not disclose or suggest "a method of prevention...." or a method of preventing..." as recited by currently amended claims 25 and 30, Applicant argument is not found persuasive because Lorant teaches an effective amount of lycopene is administered to a subject in need thereof to treat pathologies associated with androgen signaling such as acne (please note that since applicant is claiming the use of lycopene as a prophylactic, the administered of Lorant's lycopene as a prophylactic to a subject in need thereof would read on treating or preventing any and/or all diseases instead of only treating or preventing the claimed pathologies associated with androgen signaling). Lorant does not expressly teach the combination of lycopene and vitamin c administered to a subject in thereof to treat pathologies associated with androgen signaling such as acne. However, De Salvert is referenced by examiner to remedy Lorant's deficiency. De Salvert benefically teaches vitamin c treats pathologies associated with androgen signaling such as acne. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Lorant to include the claimed active ingredient of vitamin c as taught by De Salvert within Lorant's method teachings because the above combined reference would create the claimed invention of a method of treatment of symptoms or pathologies associated with androgen signaling such as acne which comprises administering to a subject in need of such treatment for therapy an effective amount of the combination of lycopene and vitamin c. Moreover, as discussed in MPEP Section 2114.06, "it is prima facie obvious to combine two or

more compositions each of which is taught by the prior art to be useful for the same purpose (i.e. to treat acne), in order to form a third composition to be used for the same purpose..." Furthermore, the adjustment of other conventional working conditions (e.g. the claimed active ingredients within various amounts within the claimed composition's method of use and the amounts and times per day the claimed composition's method is administered), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RANDALL WINSTON whose telephone number is (571)272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RW

/Christopher R. Tate/
Primary Examiner, Art Unit 1655